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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,284	02/07/2005	Gesine Schliecker	I-2002.001 US	5686

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com
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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/501,284	SCHLIECKER ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see below.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618

Claims 1-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Lewis (US 5,838,571) and in further view of Suzuki et al. (US 6,015,789) and Remington's Pharmaceutical Sciences 1990 18th Ed. Chpt. 89.

Applicant asserts that the references cannot render obvious amended claims 1,14,24 and 26, as neither references themselves nor the inferences and creative steps that a person of ordinary skill in the art would have employed at the time of the invention taught or suggested a polytartrate composition having "a lag phase of a predetermined time" in the release of a pharmaceutical composition as recited by amended claims 1,24,26, or actually "determining a time length of the lag phase" as recited by amended claim 14.

Krone et al. teaches polytartrate formulations which may comprise tablets formed via compaction/compression and do not comprise a barrier structure. Krone et al. teaches that polytartrate preparations have a decreased "initial burst" which implies that they have a second burst/release. In regards to the "lag time" the specification recites (p13, lines 17-20 and 30-33), "a secondary "lag phase" of low or no release of the drug followed by a second burst". Therefore, the polytartrate tablet formulations which are prepared via compaction/compression of Krone et al. encompass the composition of the instant claims as they have a first "initial burst", an implied second burst and the phase between the bursts (i.e. lag phase) which may release drug. Therefore, the time between bursts of the polytartrate formulations of Krone et al. encompass the "lag phase" of the instant claims.

Also, the recitation, "determining a time of the lag phase", is a mental step and does not contain any active technique (manual steps) for determining a time of the lag phase. There are no specific active steps to define how such determining is performed or which limit the amount of time of the lag phase.

Applicant asserts that Krone et al. teaches that in general after a considerable "initial burst" only a small to moderate release rate is effected. Thus, Krone et al. teaches that there can be an "initial burst" followed by a steady state rate without the need for any subsequent burst, that nothing in the cited references implies that an "initial burst" must be followed by a second burst as would be understood by one of ordinary skill in the art and that the "initial burst" simply refers to the immediate release of the available pharmaceutical from the composition, which is then followed by a more sustained slow or moderate release rate.

Krone et al. teaches that in general after a considerable "initial burst" only a small to moderate release rate is effected with regards to the prior art polyester degradable polymer pharmaceutical systems (Krone et al. column 1, lines 41-42).

Krone et al. teaches polytartrate formulations which may comprise tablets formed via compaction/compression and do not comprise a barrier structure. Krone et al. teaches that polytartrate preparations have a decreased "initial burst" which implies that they have a second burst/release. In regards to the "second burst", the specification recites that the "second booster dose (burst)" (p6, lines 1-7; p13, lines 14-16) occurs over a period of, preferably, 1-4 days while the "initial burst" occurs over 1-3 days.

According to the specification, a burst occurs over a period of days and therefore the steady state release rate/moderate release, as asserted by the applicant, of the "second burst" of Krone et al. encompasses the "second burst" of the instant invention.

The instant claims 1-18,21,22 and 24-26 do not recite a "second burst".

Applicant asserts that Krone et al. teaches compositions displaying "a strongly decreased 'initial burst' when they were used for depot preparations of pharmaceuticals" and thus teaches away from the claimed compositions as the "initial burst" is unwated.

Krone et al. teaches that the initial active substance release (initial burst) over 24 hours may be 55% (column 15, table 1 and lines 29-39).

The specification recites that the "initial burst" occurs over 1-3 days (p12, lines 22-24) and therefore the initial burst of Krone et al. (55% over 24 hours) encompasses the initial burst of the instant invention (over a period of 1-3 days).